Individual Safety Report

*3549358-6-00-01*

McNeil Consumer Healthcare

McNeil Consumer Healthcare
ort Washington, PA 19034-2299

Page ____ of ____

Approved by FDA on 11/15/93

Mfr report #

UF/Diet report #

FDA use only

## A Patient information

| 1. Patient identifier | 2. Age at time of event: / or Date of birth: | 3. Sex | 4. Weight |
|---|---|---|---|
| unknown<br>In confidence | unknown | (X) female<br>( ) male | unk lbs<br>or<br>kgs |

## B Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

( ) death (mo/day/yr)
( ) life-threatening
( ) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
(x) other: none

3. Date of event (mo/day/yr): unknown

4. Date of this report (mo/day/yr): 11/19/99

5. Describe event or problem

Psychiatrist report of OVERDOSE (12 tablets/day for 3 months) and LIVER FUNCTION TESTS ABNORMAL (increased liver enzymes by as much as 8x) allegedly associated with the use of one of our Extra Strength TYLENOL® acetaminophen products. No further information was provided.

6. Relevant tests/laboratory data, including dates

unspecified date: liver enzymes reportedly increased as much as 8x normal

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

unknown

## C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL product

#2

2. Dose, frequency & route used

#1 6000 mg, od, po

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 unknown dates; 3 mo

#2

4. Diagnosis for use (indication)

#1 overdose

#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes (X) No ( ) N/A

#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)

#1 unknown

#2

7. Exp. date (if known)

#1 unknown

#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

unknown

## G All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-273-7303

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
( ) consumer
(x) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr): 11/17/99

5. (A) NDA # 19-872
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day ( ) 15-day
( ) 10-day (X) periodic
(X) Initial ( ) follow-up #

8. Adverse event term(s)

OVERDOSE LIVER FUNC ABNO

9. Mfr. report number

1272294A

## E Initial reporter

1. Name, address & phone #

Dr. [redacted]
[redacted] Avenue
[redacted]

[redacted]

AUG - 9 2000

| 2. Health professional? | 3. Occupation | 4. Initial reporter also sent report to FDA |
|---|---|---|
| (X) Yes ( ) No | psychiatrist | ( ) Yes ( ) No (X) Unk |

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

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